

Insights

LESSONS FROM THE GROWTH OF FEMTECH AND WOMEN'S HEALTH

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SUMMARY

BCLP's Healthcare & Life Sciences Practice Group recently partnered with EMIG Digital Health Group to co-host an in-person breakfast seminar and networking event focused on FemTech. Specialists from across the FemTech and wider digital health, pharma and life sciences sectors heard speakers from Flo Health, Apricity and Theramex, amongst others, discuss key themes and lessons learnt from the growth of FemTech. Chaired by Darren Spevick, Managing Director of Russell Strategy Partners, topics discussed included the ecosystem and market and how innovation, effective partnerships, high quality content, and a simple and tangible digital strategy can drive growth in the sector. Attendees also heard from members of BCLP's dedicated FemTech team about the current themes in, and the direction of travel for, UK and EU privacy and data protection and how robust compliance can help to fuel trust and drive value.

A UNIQUE ECOSYSTEM AND MARKET

It is well documented that, historically, women's health and wellbeing has been overlooked within scientific and medical communities. The exclusion of women from clinical trials until as recently as 1993 is just one example of this. "It was thought that hormone fluctuations would affect the outcome of the trials, so we have decades of clinical research devoted to the male body and the belief that what's going to work for one sex will work for another," Strategy Advisor to FemTech companies and investors, Aahuti Rai, explained.

Whilst the legacy of under-research is changing, the scales have not yet rebalanced fully. For example, although women constitute 70% of chronic pain patients, 80% of research on pain medication has only been carried out on male humans and male mice. Just 12% of Alzheimer's research centres on women. Only 2.5% of publicly funded research in the UK is focused on reproductive health, despite 33% of women suffering severely from reproductive health issues during their lifetime. The gender health gap therefore persists. "More and more evidence is coming to light that women spend a greater part of their life in disability and ill health compared to men,"

Aahuti Rai explained. Even when women do seek help, research shows that their concerns tend to be "dismissed, misdiagnosed or missed altogether," she said.

FemTech is seeking to plug the gender health gap and, in doing so, is redefining the delivery of healthcare to "50% of the population", Aahuti stated. However, it is also important to see the bigger picture – while people usually think about ovarian or breast cancer, menopause, fertility or contraception when they hear the words "women's health", there are many other conditions and concerns that are not exclusive to women but have been shown to disproportionately affect them, such as anxiety, depression and UTIs. Other examples include osteoporosis, which is four times more common in women over 50 than men, and auto-immune diseases, like lupus and rheumatoid arthritis, which women are at a four times greater risk of developing.

Additionally, there are conditions that manifest differently in women such as Alzheimer's, diabetes and cardiovascular disease and, in some cases, women have different responses to treatment. "Within five years of having a heart attack, 47% of females will die or have a stroke, compared to 36% of males. That has to feed in to how women are considered in the healthcare system when they're receiving their care."

Funding is another significant issue, as is awareness, education and understanding, with significant taboos remaining around women's health. "One in four women who reach menopause when they're still working consider leaving the workforce – and one in ten do – because their workplace environment just isn't conducive to them being able to manage their health in this transitionary period." The gender pay gap, together with the lack of public funding for health services, has led to many women's health requirements remaining unmet. One example of this is funding constraints within the NHS which contributed towards the Government's recent decision to reject a plan for mandatory menopause training for GPs.

A NEW DAWN FOR FEMTECH

The challenges in the sector have inspired innovation and with more than 280,000 female-led women's health start-ups globally, the FemTech industry is forecast to be a trillion-dollar sector by 2027. These FemTech innovators are applying technology, whether AI, software-only or a hardware device, to address a range of challenges, from prevention and detection to self-management, diagnosis and treatment.

One example of a highly innovative model is the remote fertility clinic, Apricity. Egg freezing, egg donation, IVF and surrogacy are rarely NHS-funded, usually very expensive and often a postcode

lottery in terms of availability, said **Apricity's Head of Marketing, Nicole Campbell-Leeds**. She explained that Apricity's core mission is to address this gap by "bringing equitable access to people across the UK."

One in six couples will experience infertility, which takes an enormous toll on their lives, and Apricity's aim is to use technology to ease this journey, she said. The reality of a physical fertility clinic is inconvenient for most people, with patients expected to attend up to 20 times on average per treatment cycle. Apricity allows for many procedures to be carried out at home – assisted by nurses in person or remotely – and with virtual consultations with doctors and use of Al to guide decision making and help with embryo selection. Apricity's IVF success rate for 2023 was 42%, compared to a national average of 31%, she pointed out.

Continuing the topic of innovation, Flo Health, a period tracker with a user base of 350 million users, launched an award-winning Anonymous Mode in response to the changing legislative landscape, becoming the first female health app to take this level of precaution in terms of privacy and security. "It does mean you lose [the data] if you go to another phone, but it's a trade-off," explained Director of Medical Affairs and Partnership at Flo Health, Kym Jacks-Bryant.

Another crucial driver in the FemTech space is effective partnership, Kym added. Flo Health has a significant amount of educational content, and has worked with pharma, clinical development, telehealth and other players. While partnerships are central to driving growth, understanding where organisations fit into the ecosystem is vital, she explained. "When you're talking to an early-stage start-up they might be very interested in something that's not necessarily revenue-generating — they might just need good content and expertise." Kym went on to stress the importance of each partner therefore being upfront about expectations — "be open and honest about what you really want to achieve and be realistic about timings and resource."

Consultant at Theramex, Stephanie Clapham. "But that also means lots of choices and opportunities to focus on different areas." Theramex is a fully standalone women's health pharma company with the "sole purpose of supporting the health needs of women at every stage of their life," and which now has 6 million patients across 57 countries. One of Theramex's main focuses is to make information and education accessible, which requires not only high-quality content but "a very simple, very tangible digital strategy".

One key lesson is to invest in easy-to-use technologies, Stephanie stressed. "One of the biggest mistakes is investing in technologies that are too complicated for the age of the company. It's far

better to collaborate with partners with expertise in those spaces – it really allows you to move faster. There are so many opportunities to learn and share."

COMPLEX AND EVOLVING LEGAL CHALLENGES, BUT WITH THE OPPORTUNITY TO ADD VALUE

From a legal perspective, there is complexity – a highly regulated tech space with a myriad of approaches in different markets, the need to secure and protect IP rights and, perhaps most pertinent given recent developments, a focus on privacy and data protection.

It is easy to see why the UK GDPR and the Data Protection Act are so relevant to the FemTech space, said **BCLP Partner and UK Lead for Data Privacy and Security, Kate Brimsted**. Many apps collect the user's name, age, weight, location, contact details and perhaps even a photo, and GDPR legislation is explicit that a clear and lawful basis has to be identified for the processing of such personal data by the tech provider. Companies have to be transparent with users about what the data will be used for and who it will be shared with, and there must also be appropriate security measures in place to protect that data, she stated.

A special sub-set of data that is even more highly protected includes areas such as health, sex life and sexual orientation, and this could require explicit consent – "quite a high bar to achieve," she said. "Depending on the particular FemTech app, users might be sharing details of a medical precondition, menopause symptoms or even fertility aspirations." A recent UK survey by the Information Commissioner's Office (ICO) of more than 1,000 women about their views on using fertility tracking apps found that the security of their data and transparency around how it would be used were more important to them than the app's price or ease of use. Security breaches which affect personal data of an app's users will likely need to be reported to the ICO within 72 hours, she stated. If the security incident involves health data, it is likely that the affected users themselves will also have to be informed.

Customisation of information supplied to app users is now de rigueur, added her colleague **Anna Blest, BCLP Senior Knowledge Lawyer, Commercial, Technology and Government Affairs,** and delivering this is inevitably "very much dependent on the data you hold about your users." Developers want to create a user experience that feels friendly and relevant, but this requires trust. "The key to creating that trust is: does the user understand what you're going to be doing with the data, and who you're sharing it with?"

"Sharing" in this context is less about directly handing personal data to third parties, and more about providing digital advertisers with the ability to place cookies on user profiles. "With FemTech apps the data being shared is quite sensitive – you wouldn't necessarily want your menstrual history or many of the labels attached to you by digital marketers being shared further with data

brokers in the digital advertising ecosystem." Again, transparency is key, she stressed – giving people choice in terms of how much data they share in exchange for a better user experience – and there is a fine balance between generating revenue through digital advertising and the loyalty of users.

"As ever, best practice is a combination of carrot and stick," said Kate Brimsted. Ethical and trust-building behaviour from the outset could give a real competitive advantage, while on the 'stick' side the regulator was clearly showing an interest in the sector, with fines likely to be higher where sensitive personal data is involved. Data minimisation is also important, she pointed out. "You can't lose data you haven't collected. So think quite hard about how much data you're asking your users for, and limit it to what's really useful to you."

FINAL THOUGHTS

Digital health focused on women's health and wellbeing has experienced quite a journey. Certainly, since Ida Tin launched her period tracking and fertility app Clue in 2016, and with it coined the description "FemTech". It is a journey through a unique and evolving ecosystem and market, characterised by well documented challenges and legal and regulatory complexity. Nonetheless, the FemTech industry has experienced growth and success in a relatively short period of time. Innovation, effective partnerships and growing understanding are helping to meet previously unaddressed and underserved needs, improving diagnoses and delivery of care, breaking down stigmas and creating improved data sets that are, in turn, inspiring further focused research and facilitating investment. As FemTech enters a new dawn, it is forecast to be a trillion-dollar sector by 2027. As the industry scales, the path ahead will present new challenges and opportunities – but the destination will remain the same, to empower women to live their best lives.

ON THE HORIZON

To read more about the key UK and EU themes relevant to FemTech, and the current direction of travel in privacy and data protection, please look out for our forthcoming Legal Briefing.

The BCLP FemTech team is also offering an additional complimentary US webinar that will examine legal and related-business issues that arise the US FemTech market. To register, contact Jennifer Hutchens at Jennifer.hutchens@bclplaw.com.

MEET THE HOSTS

BCLP's Global Healthcare & Life Sciences Practice is a leader in providing legal services to support innovation across the healthcare industry. We utilize our deep strategic, operational and compliance expertise to truly partner with our clients to help them achieve their goals, including providing practical, business-focused guidance on regulatory issues, developing and executing their transactions and partnerships, and representing our clients in high-stakes and mission-critical litigation and risk management matters. The BCLP FemTech team is a dedicated sub-sector team within BCLP's Global Healthcare & Life Sciences Practice. It is comprised of specialists across various jurisdictions who appreciate the complexities and support that stakeholders in the FemTech sector need when navigating their goals.

EMIG

EMIG is a multi-stakeholder network and trade association that represents the interests of over 200 life science companies in the UK. Members range from new business start-ups focused on R&D, through to well-established companies delivering a wide range of essential medicines to patients. The EMIG Digital Special Interest Group was established in 2016 and focuses on understanding and informing EMIG members of the latest developments across digital health and digital marketing.

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Russell Strategy Partners supports business and professional service firms to help them be better at business development. Whilst many of our clients have a strong interest in the life science, pharmaceutical and healthcare sector, we also work with companies across other sectors.

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